

## Section II (Remarks)

### Amendment of the Claims

Claims 12, 13, 15, 16, 32, 33, 35 and 36 have been canceled herein, and claims 1, 14, 22, 34, 42, and 47 have been amended to further patentably delineate the subject matter recited therein.

The limitations introduced in claims 1, 14, 22, and 34 are fully consistent with and supported by the originally filed disclosure of the application. No new matter (35 USC 132) has been added.

Claims 1 and 22 now recite, inter alia, “a second layer consisting essentially of polyethylene overlying, in contact with and sealed to the first layer over its entire contacting surface, said second layer (i) being non-porous to passage of gas therethrough and (ii) comprising a peelable film consisting essentially of polyethylene in direct facial contact with the first layer of porous material.” Such amendatory changes are supported by the disclosure page 7, paragraph [0020], lines 7-8 (“the peelable sheet... desirably is a peelable polyethylene sheet”), page 9, paragraph [0027], lines 4-5 (“a backing material, e.g., polyethylene”) and lines 5-6 (“[T]he overlying sheet 18 remains in sealing contact with the porous sheet 26”), FIG. 1 and appertaining disclosure at page 8, paragraph [0025] to page 9, paragraph [0027] (showing peelable sheet 18 including peelable layer 24 in direct facial contact with the porous sheet 26 over the full contacting surface of the peelable layer) and FIG. 2 and appertaining disclosure at page 9, paragraph [0029] (showing sheet 32 overlying porous material sheet 34 over the entire contacting surface of sheet 32).

Claims 14 and 34 have been amended to recite the second later as comprising a backing layer “consisting essentially of polyethylene.” Such limitation is supported by the disclosure at page 9, paragraph [0027], lines 4-5 (“a backing material, e.g., polyethylene”).

Claims 42 and 47, dependent (directly or indirectly) from claim 22, have been amended for consistency therewith, by deletion of the compositional limitation on the peelable film.

As thus amended, claims 1-11, 14, 17-31, 34 and 37-49 are now in form for allowance, consistent with the distinguishing remarks directed to such claims in the ensuing section.

**Rejection of Claims on Reference Grounds, Traversal Thereof in Application to the Amended Claims, and Patentable Distinction of the Amended Claims over the Cited References**

In the August 2, 2005 Office Action, claims 1-49 were rejected on reference grounds, including:

- a rejection of claims 1-2, 5-6, 10, 12-22, 25-26, 30, 32-41 and 43-46 under 35 USC §102(b) as anticipated by Hirsch et al. U.S. Patent 4,055,672 ("Hirsch");
- a rejection of claims 1-2, 5-22, 25-36, 40 and 43-46 under 35 USC §102(b) as anticipated by Anderson et al. U.S. Patent 5,418,022 ("Anderson");
- a rejection of claims 3-4 and 23-24 under 35 USC §103(a) as unpatentable over Hirsch in view of Brown et al. U.S. Patent 5,217,772 ("Brown");
- a rejection of claims 7-9, 11, 27-29, 31, 42 and 47-49 under 35 USC §103(a) as unpatentable over Hirsch in view of Anderson; and
- a rejection of claims 3-4 and 23-24 under 35 USC §103(a) as unpatentable over Anderson in view of Brown.

These rejections of the claims are traversed, and reconsideration of the patentability of the claims as amended herein is requested, in light of the following remarks.

Claims 1 and 22, as amended herein, from which pending claims 2-11, 14, 17-21, 23-31, 34 and 37-49, and variously depend, recite

"a first layer of a porous material" and "a second layer consisting essentially of polyethylene overlying, in contact with and sealed to the first layer over its entire contacting surface, said second layer (i) being non-porous to passage of gas therethrough and (ii) comprising a peelable film consisting essentially of polyethylene in direct facial contact with the first layer of porous material."

No such structure is taught or suggested in any of the references of Hirsch, Anderson, or Brown, taken singly or in any permutative combination thereof.

Hirsch, cited singly as anticipating claims 1-2, 5-6, 10, 12-22, 25-26, 30, 32-41 and 43-46 as previously pending, has been cited for teaching of packaging structure including an impermeable layer 24 and an adhesive layer 26, as being in facial contact with a layer 22 of porous material. Neither of such layers 24 or 26 consists essentially of polyethylene. Contrariwise, layer 24 is disclosed in Hirsch as having the following composition:

"Outer gas barrier layer 24 must be selected from gas impermeable materials such as polyester, nylon, cellophane, polypropylene, polyvinyl acetate, saran or combinations of the aforementioned materials with each other or in further combination with polyethylene, ethylene vinyl acetate copolymer, ionomer, or coextrusions involving two or more of the aforementioned polymeric materials. The outer permeable layer 24 may also be formed from materials and combinations of materials similar to those employed to form the tray 12." (column 4, lines 56-65 of Hirsch)

Thus, it is seen that Hirsch teaches away from use of polyethylene per se, specifically teaching that polyethylene is used only in combination with other materials such as polyester, nylon, cellophane, polypropylene, polyvinyl acetate, saran, etc. It also is noted to that the materials disclosed by Hirsch for construction of tray 12, as referenced in the above quote, likewise, disclose polyethylene only in combination with other polymeric materials. See column 3, lines 52-63, of Hirsch.

Further, the layer that is in direct facial contact with the porous layer in Hirsch is, as acknowledged by the examiner, an adhesive layer. Hirsch discloses the composition of such layer at column 5, lines 14-30:

"The adhesive layer is preferably selected from natural or synthetic rubber-based adhesives applied from conventional organic solvent solutions although a variety of adhesives may be employed. Ordinarily, the adhesive layer will be tackified with appropriate resins and may be plasticized with compatible plasticizers as is well known in the art. Among the adhesives which may be adapted for use in the package of the invention, are vinylbased thermoplastic adhesives, pressure-sensitive adhesives prepared from natural or synthetic rubbers in conjunction with tackifiers and plasticizers, polyurethanes, heat seal coatings derived from vinyl acetatic copolymers of polyethylene modified with microcrystalline waxes and resins, polyethylene imine primers, and various butyl rubber-resin blends. Such adhesives are well known in the art and are commercially available." (Hirsch, column 5, lines 14-30)

As is apparent from the above-quoted disclosure of Hirsch, such reference discloses polyethylene only in the context of "heat seal coatings derived from vinyl acetatic copolymers of polyethylene modified with microcrystalline waxes and resins." Such wax- and resin-modified derivatives of vinyl acetatic copolymers do not constitute or suggest a film "consisting essentially of polyethylene indirect facial contact with the first layer of porous material," as required by all of applicants' claims 1-11, 14, 17-31, 34 and 37-49.

Anderson has been cited as teaching a peelable film 20 and a porous material 12 in direct contact at area

30 of the structure shown in FIG. 1 of such reference. The peelable film 20 of the Anderson, however, is not "in contact with and sealed to the first layer over its entire contacting surface," as required by all of applicants' pending claims 1-11, 14, 17-31, 34 and 37-49. Contrariwise, the peelable film 20 of Anderson is sealed to a pocket-forming structure over only a very small part of its surface (see FIG. 1, in which peel seal area 30 is a stripe around the pocket to 40) "by adhesives or heat sealing" as described by Anderson at column 2, lines 13-18. There is therefore no derivative basis in Anderson for applicants' claimed invention.

Brown has been cited in combination with Hirsch in rejecting claims 3-4 and 23-24, Brown having been cited specifically for teaching of a cellulosic paper as a gas permeable layer (see page 12 of the March 7, 2005 Office Action).

The mere importation of a cellulosic, e.g., paper, layer into Hirsch, however, does not change the fact that the resulting hypothetical combination would still lack "a second layer consisting essentially of polyethylene overlying, in contact with and sealed to the first layer over its entire contacting surface, said second layer (i) being non-porous to passage of gas therethrough and (ii) comprising a peelable film consisting essentially of polyethylene in direct facial contact with the first layer of porous material," as is required by claims 3 and 4, by virtue of their dependence under claim 1, and as is required by claims 23 and 24, by virtue of their dependence under claim 22.

Hirsch in view of Anderson has been cited as a basis for rejection of claims 7-9, 11, 27-29, 31, 42 and 47-49. These dependent claims, however, all require, inter alia, "a second layer consisting essentially of polyethylene overlying, in contact with and sealed to the first layer over its entire contacting surface, said second layer (i) being non-porous to passage of gas therethrough and (ii) comprising a peelable film consisting essentially of polyethylene in direct facial contact with the first layer of porous material," by virtue of their dependence under independent claims 1 (in the case of claims 7-9 and 11) and 22 (in the case of claims 27-29, 31, 42 and 40 7-49).

Hirsch and Anderson are in no way combinable to yield such a layer structure. As noted hereinabove, Hirsch teaches away from use of polyethylene per se, specifically teaching that polyethylene is used only in combination with other materials such as polyester, nylon, cellophane, polypropylene, polyvinyl acetate, saran, etc. and Hirsch teaches an adhesive layer layer in direct facial contact with the porous layer, as acknowledged by the examiner. Thus, the examiner's hypothetical combination of Hirsch and

Anderson as including a TYVEK porous layer as taught by Anderson (see page 14 of the March 7, 2005 Office Action) would still not yield the layer structure required by applicants' amended claims.

Concerning claims 48 and 49, the examiner has proposed the combination of Hirsch and Anderson as motivating the skilled artisan "to select the bond and sealing strengths between the first layer and the second layer and non-porous panel, respectively in the ranges taught in claims 48 and 49, because the requirements presented for the bond and seal strengths in Hirsch et al. are the same requirements as the claimed invention" (page 15 of the March 7, 2005 Office Action).

Applicants traverse such basis of rejection, on the ground that Hirsch does not in fact teach a bond strength greater than about 20 Newtons per 15 mm bonded edge region width, as required by claims 48 and 49. Hirsch merely teaches that the heat seal between tray 12 and inner layer 22 is maintained "in excess of 5 lbs. per inch," which by application of appropriate conversion factors means that such heat seal is in excess of 13.135 Newtons per 15 millimeters. Thus, the value stated by Hirsch is less than 66% of the value required by claims 48 and 49. The examiner's attention is directed to the discussion of the present invention in paragraph [0019] bridging pages 6 and 7 of the instant application:

[0019] "In this respect, it is to be noted that standard Tyvek® peel pouches the peelable layer thickness and seal temperatures are selected to obtain an opaque seal with a limited seal strength that is typically on the order of 5 Newtons/15 millimeters seal width. In the case of isolator bags or other Tyvek® bags that need integrity testing, the seal strength needs to be substantially higher, e.g., on the order of at least 20-25 Newtons/15 millimeters seal width. Such higher seal strength in turn requires a transparent seal that necessitates higher temperature for sealing. Since the making of the transparent seal requires higher temperatures, the construction of the peelable film must be modified in order to avoid damage to the peel layer. The present invention therefore embodies a substantial departure from the methods of the prior art that have been employed to form standard Tyvek® peel pouches, further evidencing the inventive character of the containment structures and package articles of the present invention."

The foregoing reflects the applicants' invention has directed to packaging that is adapted for integrity testing by pressure retention assessment, requiring a markedly higher (over 50% higher) seal strength than is contemplated by Hirsch. The seal strength level recited in claim 48, from which claim 49 is dependent, therefore finds no derivative basis in Hirsch.

Finally, concerning the rejection of claims 3-4 and 23-24 over Anderson in view of Brown, such rejection has been premised on utilizing paper in place of TYVEK in the sterilizable package of Anderson et al., based on the examiner's assertion that "Brown et al. teach that it is notoriously well-known in the art of packaging of medical supplies that are subjected to sterilizing gas while within the package to substitute paper for TYVEK as the gas permeable layer, depending on the intended in result of the product" (page 16 of the March 7, 2005 Office Action), citing Brown et al. at column 5, lines 10-15.

In fact, Brown does not characterize any disclosure therein as "notoriously well-known in the art," but merely states that the the Web 20 "may consist of Tyvek or any other fibrous material such as cardboard, paperboard, or the like."

As was also the case in the previously discussed rejection of claims 3-4 and 23-24 based on the Hirsch in view of Brown, the mere importation of paper (from Brown) in place of TYVEK in Anderson, however, does not change the fact that the resulting hypothetical combination would still lack "a second layer consisting essentially of polyethylene overlying, in contact with and sealed to the first layer over its entire contacting surface, said second layer (i) being non-porous to passage of gas therethrough and (ii) comprising a peelable film consisting essentially of polyethylene in direct facial contact with the first layer of porous material," as is required by claims 3 and 4, by virtue of their dependence under claim 1, and as is required by claims 23 and 24, by virtue of their dependence under claim 22.

The peelable film 20 of the Anderson is not "in contact with and sealed to the first layer over its entire contacting surface," as required by all of applicants' pending claims 1-11, 14, 17-31, 34 and 37-49. Contrariwise, the peelable film 20 of Anderson is sealed to a pocket-forming structure over only a very small part of its surface (see FIG. 1, in which peel seal area 30 is a stripe around the pocket to 40) "by adhesives or heat sealing" as described by Anderson at column 2, lines 13-18. There is therefore no derivative basis in Anderson in view of Brown for applicants' claimed invention.

### CONCLUSION

Based on the foregoing, all of applicants' pending claims 1-11, 14, 17-31, 34 and 37-49 are therefore patently distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,



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